Testimony of

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The Report of the National Bioethics Advisory Commission on *Ethical Issues in Human Stem Cell Research*

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Good morning, Mr. Chairman and members of the subcommittee. I am James Childress, a member of the National Bioethics Advisory Commission (NBAC) and the Kyle Professor of Religious Studies at the University of Virginia. I am pleased to testify before you this morning on behalf of NBAC on the subject of its recent report, *Ethical Issues in Human Stem Cell Research.* I know you are aware that on two previous occasions NBAC has testified before your subcommittee, providing updates on the status of this report. Today I will briefly describe the background and process we used to arrive at our recommendations, and summarize some of our major recommendations. Copies of the Executive Summary of the report have been distributed to the Committee and are also available on NBAC's website, at www.bioethics.gov.

Background and Process

On November 14, 1998, President Clinton wrote to NBAC, requesting that we "undertake a thorough review of the issues associated with . . . human stem cell research, balancing all ethical and medical considerations." From then, until September 1999, when the commission submitted its report, we spent most of our time examining the full range of issues associated with human stem cell research in order to reach the best judgment we could about the appropriate balance of "ethical and medical considerations" and about the appropriate ethical and policy guidelines for such research.

We believed that it was necessary to get as clear a picture as possible about the science involved and about the possible medical benefits of research on human stem cells, in light of the reports about a year ago that researchers had isolated and cultured human embryonic stem cells (or ES cells) and embryonic germ cells (or EG cells). Our initial meetings included testimony from Dr. Harold Varmus, Dr. John Gearhart of Johns Hopkins University, Dr. Jamie Thomson of the University of Wisconsin, and others. It became clear to us that the published reports of isolating ES and EG cells generated considerable scientific and clinical interest because of the prospect that human stem cells could be used to produce more specialized cells or tissue to treat injuries or diseases such as Alzheimer's disease, Parkinson's disease, and heart disease. The research also could further the development of life-saving drugs and other therapies and increase our understanding of the earliest stages of human development.

While creating great excitement, particularly because of its medical promise, this research also raised serious ethical concerns, mainly because the major current sources of stem cells are cadaveric fetal tissue obtained from elective abortions, and embryonic tissue derived from embryos remaining after *in vitro* fertilization (IVF).

In exploring the scientific, medical, and ethical issues, NBAC benefited from broad and diverse testimony, in both oral and written form, by experts and the public. All of NBAC's meetings are held in public and provide ample opportunity for public input. Indeed, NBAC's deliberations about how to balance ethical and medical issues were informed throughout by perspectives provided by members of the public, as well as by interpreters of major religious traditions, philosophers, bioethicists, lawyers, scientists, physicians, and others. Of the many experts who provided valuable testimony to the Commission, one group offered particularly helpful perspectives. On May 7, 1999 NBAC convened a meeting at Georgetown University to hear presentations on religious perspectives relating to human stem cell research. Altogether eleven scholars in Roman Catholic, Jewish, Eastern Orthodox, Islamic and Protestant traditions presented formal testimony that day, and two others made statements in the public comment period. The diversity of views, both across these traditions and within them, suggested to us that there are different perspectives, from longstanding religious traditions, about the ethical acceptability of research on cadaveric fetal tissue and on the human embryo.

With specific attention to the ethical issues, NBAC found widespread agreement that "human embryos deserve respect as a form of human life" (p. 90) but, at the same time, disagreements "regarding both what form such respect should take and what level of protection is required at different stages of embryonic development." At the very least this "respect" means that these sources should not be used unless they are necessary for research, that cadaveric fetal tissue and embryos remaining following IVF should not be bought or sold, and that alternative sources should simultaneously be explored. In addition, NBAC sought to show respect for the range of serious ethical concerns represented in various positions on stem cell research in our society.

NBAC's deliberations reflected the "tension" that many experience between the ethically grounded desire to realize the promise of therapeutic benefits of this research and the ethically grounded desire to treat the different sources of stem cells with appropriate respect. Because of these important ethical concerns, NBAC "wrestled" with the strong arguments presented for and against the derivation and use of stem cells from different sources in its efforts to formulate an acceptable public policy regarding federal funding of and guidelines for such research.

NBAC's Recommendations

Our report made 13 recommendations in several areas.

We concluded that it would be appropriate for the federal government to provide funds for the derivation and use of EG and ES cells from cadaveric fetal tissue and from embryos remaining after infertility treatments. Building on current policies and practices relating to fetal tissue transplantation, NBAC recommends that research involving the derivation and use of human EG cells from cadaveric fetal tissue, following deliberate

abortions, "should continue to be eligible for federal funding," and that the "relevant statutes and regulations should be amended to make clear that the ethical safeguards that exist for fetal tissue transplantation also apply to the derivation and use of human EG cells for research purposes" (Recommendation # 1). These "ethical safeguards" were erected to prevent the use of fetal tissue in transplantation research from encouraging abortions. For example, they separate the consent process for abortion from the consent process for the donation of fetal tissue for research and prohibit the donor of fetal tissue from designating the recipient of the transplant. These guidelines appear to be sufficient in human fetal tissue transplantation research and should be extended to stem cell research as well.

A second source of stem cells—ES cells from embryos remaining after infertility treatments—is more controversial because the derivation of ES cells destroys the embryo. NBAC proposes that "research involving the derivation and use of human ES cells from embryos remaining after infertility treatments should be eligible for federal funding" (Recommendation #2). To this end, NBAC recommends a limited "exception" to the current statutory ban on federal funding of embryo research to permit research that involves the derivation of human ES cells from embryos remaining after IVF. Rather than attempting to resolve the debate about the interpretation of the statutory ban on embryo research, NBAC chose to focus on the ethical concerns involved.

Our conclusion that "it is ethically acceptable for the federal government to finance research that both derives cell lines from embryos remaining after infertility treatments and that uses those cell lines" reflects our judgment, based on expert testimony, that it is a mistake to suppose that derivation and use can be "neatly separated without affecting the expansion of scientific knowledge"—instead, there is a "close connection in practical terms." For instance, the methods for deriving stem cells may affect the properties of the ES cells, and increased understanding of the nature of ES cells may come in part from the process of derivation.

Several ethical concerns arise in the derivation and use of ES cells from embryos remaining after IVF, and some are similar to those that arise in the derivation and use of EG cells from cadaveric fetal tissue. NBAC proposes ways to separate, to the extent possible, donors' decisions to dispose of their embryos from their decisions to donate them for research, in order to reduce the possibility that "potential donors could be pressured or coerced into donating their embryos for stem cell research." We stress that "potential donors should be asked to provide embryos for research only if they have decided to have those embryos discarded instead of donating them to another couple or storing them. If the decision to discard the embryos precedes the decision to donate them for research purposes, then the research determines only how the destruction occurs, not whether it occurs."

We also recommend (Recommendation # 5) the disclosure of certain, specific information to those considering whether to donate their embryos for research. The informational components include: the ES cell research "is not intended to provide medical benefit to embryo donors"; a decision to donate or not to donate the embryos for research will not affect future care provided to the prospective donors; "the research will involve the destruction of the embryos"; and the "embryos used in research will not be transferred to a woman's uterus." In addition, we recommend (Recommendation #6) that,

in federally funded research, researchers "may not promise donors that ES cells derived from their embryos will be used to treat patient-subjects specified by the donors."

NBAC identified another ethical constraint that needs to be in place for the derivation and use of stem cells from embryos remaining after IVF as well as for research involving cadaveric fetal tissue: "Embryos and cadaveric fetal tissue should not be bought or sold" (Recommendation #7). Federal statutes and regulations and state statutes should be examined to make sure that they or subsequent modifications achieve this end.

I should note that we considered two other possible sources of human ES cells, again balancing the relevant ethical and medical considerations. We recommend against the deliberate creation of embryos for research at this time, whether by IVF (Recommendation # 3) or by somatic cell nuclear transfer cloning (Recommendation # 4). In NBAC's judgment, the creation of research embryos could not be justified at this time either on the grounds that the supply is inadequate or on the grounds that matched tissue is needed for autologous cell replacement. However, the report notes that it may be appropriate to reconsider these issues in the future (p. 93).

Most of the remaining recommendations (#8-13) focus on the creation and functions of a National Stem Cell Oversight and Review Panel, a broad, multidisciplinary panel with public members, which NBAC recommends that the Department of Health and Human Services (DHHS) establish in order "to ensure that all federally funded research involving the derivation and/or use of human ES or EG cells is conducted in conformance with the ethical principles and recommendations contained in this report." (Recommendation #8).

Conclusion

In summary, NBAC concluded that it would be acceptable for the federal government to fund research that both derives and uses stem cells from cadaveric fetal tissue and from embryos remaining from fertility treatment, if certain guidelines and safeguards are in place and if there is an appropriate and open system of national oversight and review. However, at this time it recommends against federal funding for the creation of embryos for research by either IVF or somatic cell nuclear transfer cloning.

In part because of the evolving science and on-going societal conversation about ethical issues, NBAC did not suppose that it could offer the final word on the ethics of human stem cell research, on the best possible balance of ethical and medical considerations, or on how to resolve the tension between proper respect for cadaveric fetal tissue and embryos remaining after IVF, on the one hand, and promoting research that could relieve much human suffering, on the other hand. However, our recommendations reflect our considered judgment, based on an extensive, open, and public process of obtaining information and engaging various ethical, legal, and policy perspectives, about an "acceptable public policy" that reflects "widely shared views" about not foregoing the potential benefits of stem cell research and about respecting cadaveric fetal tissue and embryos remaining after IVF as well as avoiding undue pressure, coercion, and exploitation of potential donors. Throughout its deliberations, NBAC attempted to propose policies "that demonstrate respect for all reasonable alternative points of view

and that focus, where possible, on the shared fundamental values that these divergent opinions, in their own ways, seek to affirm."

We hope that our report will further stimulate the important public debate about the profound ethical issues regarding this potentially beneficial research.

Thank you, Mr. Chairman. I would be glad to answer any questions you or the members of the Subcommittee may have.